



General

Guideline Title

Testosterone testing protocol.

Bibliographic Source(s)

Medical Services Commission. Testosterone testing protocol. Victoria (BC): British Columbia Medical Services Commission; 2011 Jun 1. 4 p.
[10 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Diagnosis/Investigation

General screening for testosterone deficiency (hypoandrogenism) in men is not recommended but should be guided by medical history and clinical examination.

Erectile dysfunction by itself is not an indication for testosterone testing. In the presence of erectile dysfunction with decreased libido and/or testicular atrophy, serum testosterone testing is indicated.

Testosterone testing is not indicated for the investigation of hypoandrogenism in women, including low libido in women.

Normal ranges for serum total testosterone and calculated bioavailable testosterone (cBAT) show method and age dependence and are determined by each laboratory independently.

Testosterone Deficiency in Males

a. Signs and Symptoms

In the presence of a clinical indication, serum testosterone measurement is appropriate. Hypoandrogenism is suggested by the following symptoms and signs.

Table: Signs of Hypoandrogenism in Males

- Incomplete or delayed sexual development, eunuchoidism.

- Reduced sexual desire (libido) and activity.
- Decreased spontaneous erections.
- Breast discomfort, gynecomastia.
- Loss of body (axillary and pubic) hair, reduced shaving.
- Very small (especially <5 ml) or shrinking testes.
- Inability to father children, low or zero sperm count.
- Height loss, fragility fracture, low bone mineral density.
- Hot flushes, sweats.

Adapted from Bhasin et al. J Clin Endocrinol Metab. 2010;95(6):2536-2559.

b. Testing

Specimens should be collected in the early morning (preferably before 10 am). Testing of serum total testosterone should be done when patients are clinically stable; avoid testing during acute or subacute illness.

Serum total testosterone is the initial test of choice. If the level is below the lower limit of normal (approximately 10 nmol/L), *and a diagnostic question remains*, cBAT can be used to confirm hypoandrogenism.

c. Diagnosis

The diagnosis of hypoandrogenism is a probabilistic process based on medical history and physical findings, followed by investigational tests, guided by the clinical findings. Further investigation to determine the etiology of hypoandrogenism in men is beyond the scope of this protocol.

d. Monitoring of Treatment

The monitoring of testosterone therapy in men is primarily clinical. The usefulness of serum testosterone testing while on treatment is controversial.

Testosterone Excess in Females

a. Signs and Symptoms

A range of symptoms and signs from hypertrichosis, hirsutism, to virilization may occur.

b. Testing

Serum total testosterone is frequently normal in women with mild clinical hyperandrogenism (due to androgen suppression of sex hormone binding globulin [SHBG] production); cBAT testing has a better diagnostic yield for testosterone excess in women. Repeat serum testosterone testing is *not indicated* if cBAT is normal. A serum total testosterone level of less than 7 nmol/L will rule out almost all of the testosterone-secreting neoplasms. Other hormonal testing is dependent on clinical findings and is beyond the scope of this protocol.

c. Diagnosis

The diagnosis of testosterone excess is based on medical history and physical findings, followed by investigational tests. Virilization that appears over a short period of time should arouse suspicion of adrenal or ovarian tumors and urgent specialist referral is advised. Further investigation to determine the etiology of androgen excess in females is beyond the scope of this protocol.

d. Monitoring of Treatment

Response to treatment of hyperandrogenism in women is clinical. Therefore, testing of serum total testosterone and cBAT in patients treated for hyperandrogenism is not recommended.

Note: See the original guideline document for the following tables:

- Conditions Associated with Alterations in SHBG Concentrations
- Medications Which May Alter Testosterone Levels in Males
- Medications Which May Increase Testosterone Levels in Females

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Testosterone deficiency in males
- Testosterone excess in females

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Intended Users

Physician Assistants

Physicians

Guideline Objective(s)

To review serum testosterone testing in adult males and females

Target Population

Adult males and females ≥ 19 years of age with suspected testosterone deficiency (males) or testosterone overproduction (females)

Interventions and Practices Considered

1. Serum total testosterone testing
2. Calculated of bioavailable testosterone (cBAT)
3. Medical history
4. Physical examination
5. Specialist referral for women with virilization over a short period of time

Note: The following were considered but not recommended:

General screening for testosterone deficiency in men

Testosterone testing in men with erectile dysfunction as the sole symptom

Testosterone testing in women to investigate hypoandrogenism, including low libido

Testosterone testing to monitor testosterone therapy

Repeat serum testosterone testing in women with a normal cBAT

Major Outcomes Considered

- Sensitivity and specificity of testosterone testing
- Incidence of comorbid conditions and abnormal testosterone levels
- Incidence of comorbid conditions and abnormal sex hormone binding globulin (SHBG)
- Incidence of medications resulting in abnormal testosterone or SHBG levels
- Incidence of abnormal laboratory results based on the laboratory and patient age, circadian rhythm, episodic secretion, exercise level, temporary illness, or eating disorder

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence was obtained through a systematic review of peer-reviewed literature (up to November 2010) using the databases MEDLINE, PubMed, EBSCO, Ovid, and the Cochrane Collaboration's Database for Systematic Reviews. Search terms include testosterone testing, hypergonadism, hypogonadism, testosterone deficiency, erectile dysfunction, serum testosterone, bioavailable testosterone and sex hormone binding globulin. Clinical practice guidelines from other jurisdictions for testosterone testing, hypergonadism, hypogonadism, testosterone deficiency, and erectile dysfunction were also reviewed (up to November 2010).

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline is an evidence-based clinical guideline for general practitioners with consensus statements when evidence is not available. It is based on scientific evidence current as of the Effective Date.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guideline was approved by the British Columbia Medical Association and adopted by the Medical Services Commission.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

This is an evidence based clinical guideline for general practitioners with consensus statements when evidence is not available. The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate of testosterone testing for adult men and women

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

The Clinical Practice Guidelines (the "Guidelines") have been developed by the Guidelines and Protocols Advisory Committee on behalf of the Medical Services Commission (MSC). The Guidelines are intended to give an understanding of a clinical problem, and outline one or more preferred approaches to the investigation and management of the problem. The Guidelines are not intended as a substitute for the advice or

professional judgment of a health care professional, nor are they intended to be the only approach to the management of clinical problems.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Medical Services Commission. Testosterone testing protocol. Victoria (BC): British Columbia Medical Services Commission; 2011 Jun 1. 4 p.
[10 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jun 1

Guideline Developer(s)

Medical Services Commission, British Columbia - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

Medical Services Commission, British Columbia

Guideline Committee

Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [British Columbia Ministry of Health Web site](#) .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 31, 2013. The information was verified by the guideline developer on March 20, 2013.

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